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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,288	04/25/2001	Herwig Buchholz	MERCK 1943	7732

23599 7590 06/29/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,288	BUCHHOLZ ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-11,13-19 and 21-28* is/are pending in the application.

4a) Of the above claim(s) *7-11,13 and 24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

I. The rejection of the claims under 35 USC 112, second paragraph, is maintained for the reason of the record.

II. The rejection of the claims under 35 USC 103(a) over Koppel (US 5358720) in view of Bailey et al. (US 5997915) is maintained for the reason of the record.

Status of Application

1. By an amendment filed February 04, 2004, claim 1 has been amended. Claims 1, 4, 6 and 14-23 are currently pending for prosecution on the merits.

2. Claims 7-11, 13 and 24-28 have been withdrawn from further consideration by the examiner as being drawn to non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is analogous to the original rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4, 6 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koppel (US 5358720) in view of Bailey et al. (US 5997915).

This rejection is analogous to the original rejection.

Response to Arguments

5. Applicant's arguments filed February 04, 2004 have been fully considered but they are not persuasive.

In response to the rejection of the claims 21 and 23 under 35 USC 112, second paragraph, applicants allege that claim 1 encompasses all isomers of the named compounds, while claims 21 and 23 name some specific isomers of the same compounds. The examiner strongly disagrees. Unlike applicant's allegation, there is absolutely no basis for any isomers of the compounds of claims 21 and 23. The scope of the instant claim 1 only encompasses "dihydrofolic acid, tetrahydrofolic acid, 5-methyltetrahydrofolic acid, 5-formyltetrahydrofolic acid, 10-formyltetrahydrofolic acid, 5,10-methylenetetrahydrogolic acid, or 5,10-methenyltetrahydrofolic acid" and their physiologically acceptable salts. The examiner does not recognize that "isomers" is equivalent to "salts" form.

In response to the rejection of the claim 22 under 35 USC 112, second paragraph, applicants allege that claim 22 depends from claim 1, it is by definition clear that the glutamic acid derivatives can only be derivatives of the compounds specified in claim 1. The examiner strongly disagrees. As stated above, the scope of the instant claim 1 only "dihydrofolic acid, tetrahydrofolic acid, 5-methyltetrahydrofolic acid, 5-formyltetrahydrofolic acid, 10-formyltetrahydrofolic acid, 5,10-methylenetetrahydrogolic acid, or 5,10-methenyltetrahydrofolic acid" and their physiologically acceptable salts. There is absolutely no basis for any derivatives of said compounds. The examiner does not recognize that "derivatives" is equivalent to "salts" form.

In response to the rejection of the claims under 35 U.S.C. 103(a), applicants allege that Koppel is non-analogous art since the subject matter of Koppel, drawn to the treatment of arthritic conditions, differs from the instantly claimed invention that is directed to compositions useful for the treatment and prevention of transmethylation disorders, preferably cardiovascular diseases such as atherogenic and thrombogenic diseases. Applicants further allege that one of ordinary skill in the art working in the field of transmethylation disorders as described above, would have lacked the motivation to consider the teachings of the reference that is directed to the treatment of certain inflammatory disorders and more particularly for the alleviation of arthritic conditions.

The examiner disagrees. It is noted that applicants' statement of intended use or purpose are not limiting to the interpretation of composition claims. Therefore, Koppel's vitamin composition is considered analogous art. The skill artisan working in the filed of nutritional supplements or vitamin compositions would have been motivated to increase poor bioavailability of folic acid in vitamin composition or nutritional supplements such that patient's compliance could be greatly improved with more uniformly absorbed form of folate. Since the interpretation of the instant claims ("A composition comprising...") allows for the inclusion of any other unspecified ingredients even in major amounts, Koppel's vitamin composition in view of Bailey makes obvious the claimed invention.

In conclusion, the examiner maintains that Bailey provides ample motivation to modify the teaching of Koppel to arrive at the claimed composition.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

VICKIE KIM
PRIMARY EXAMINER